AD_____

Award Number: DAMD17-02-1-0062

TITLE: Treatment Decision Making in Early-Stage Prostate Cancer: Evaluation of Computer-Based Patient Education and an Interactive Decision Aid

PRINCIPAL INVESTIGATOR: Kathryn L. Taylor, Ph.D.

CONTRACTING ORGANIZATION: Georgetown University
Washington, DC 20007

REPORT DATE: February 2004

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	February 2004	Annual (1 Feb 2003 - 31 Jan 2004)

4. TITLE AND SUBTITLE
Treatment Decision Making in Early-Stage Prostate Cancer: Evaluation of Computer-Based Patient Education and an Interactive Decision Aid

5. FUNDING NUMBERS
DAMD17-02-1-0062

6. AUTHOR(S)
Kathryn L. Taylor, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Georgetown University
Washington, DC 20007

E-Mail: taylorkl@georgetown.edu

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)
This study aims to examine a method of patient education for men who are seeking treatment for management of localized prostate cancer. The primary goal is to evaluate a recently developed computer-based educational tool (CD-ROM) that is designed to provide treatment-related information and to assist men in making an informed treatment decision. Once they are diagnosed with localized cancer, men are accrued post-biopsy for a baseline interview, and are randomized to receive a CD-ROM with a decision aid, or a CD-ROM with information only. To date, we have accrued and randomized 88 patients and study participation rate is currently 74.5%. We have had 16 men decline participation, 4 men withdraw from the study post-randomization, 5 men who we were never able to reach, and 5 men who are considered "missed" as they had already made a concrete treatment decision by the time we contacted them. Two changes have been made to the study protocol since lat year's review and both changes have been approved by the Georgetown IRB and were submitted to the DOD on August 11, 2003. We are now accruing men post-biopsy, whereas we had previously tried to accrue pre-biopsy and we also added a 12-month follow-up interview.

14. SUBJECT TERMS
Prostate cancer, medical decision making

15. NUMBER OF PAGES
24

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

INTRODUCTION

There is a controversy in the medical community surrounding the utility of treatment options for early stage prostate cancer. Although several options are available for management of localized prostate cancer, no option is clearly superior to others. The primary goal is to evaluate a method of patient education that is designed to provide treatment-related information and to help men clarify their preferences and values via a recently developed computer-based decision aid. We expect that men randomized to the decision aid condition will be more active in their treatment decision and will have improved patient outcomes relative to men assigned to the information-only condition.

Men will be accrued post-biopsy and those with a positive biopsy result will receive the intervention following notification of the diagnosis but prior to their initial meeting with the urologist in which treatment options are discussed. Participants will be followed at one month, six months and twelve months post-intervention. The primary outcomes include patient outcomes (knowledge, quality of life, and decisional satisfaction) and shared decision making (SDM) practices.

In many areas of medicine, including treatment of localized prostate cancer, there has been a rapid expansion of research that has resulted in a growing number of diagnostic and treatment options that are available to physicians and patients. In many cases, there are several effective and viable treatment options, but randomized clinical trials assessing treatment effectiveness have not yet been completed. Although the availability of different options will undoubtedly be beneficial in the long run, at present it creates a difficult decision for individuals and physicians who are faced with the choices for which no best answer is known. The proposed study is designed to assist the patient through this decision, by providing information and helping him consider his values.

BODY

We have listed each of the tasks from our Statement of Work, and the associated accomplishments.

Task 1. Finalize accrual procedures and measures to be included (months 1-2).

Accomplished during year one.

Task 2. Conduct participant accrual (months 3-27).

We received approval to conduct Human Subjects research in September, 2002 and began patient accrual at the Division of Urology, Georgetown University. We have accessioned eligible participants and have been conducting baseline interviews over the telephone. For those who agreed to the study and were diagnosed with early-stage prostate cancer, we completed the baseline interview and randomized them to either receive the CD-ROM with a decision aid or a CD-ROM with information only. We finalized the medical record abstraction form and have accessed patient information from medical chart review.

Task 3. Conduct follow-up assessments (months 4-33).

For those who agreed to the study, we have been administering follow-up interviews at one month post intervention, six months post intervention and twelve months post intervention. Of the 88 men who agreed to the baseline interviews and were randomized, 92% of the men have completed the one month follow-up, 91% have completed the six month follow-up, and 91% have completed the twelve month follow up.

Task 4. Preliminary data analyses and baseline manuscript (months 4-33).

We have conducted some preliminary analyses. The study participation rate is currently 74.5% (N = 76). The mean age of participants was 63.8 (±12.2). Subjects were predominantly White (75.0%), married (77.3%), college educated (78.9% college degree or beyond), medically insured (98.7%) and had computer access (97.4%). Over half of men (51.3%) reported another major illness. Mean baseline EuroQol was 80.6 (±14.5). Forty-seven men (61.8%) reported high baseline decisional conflict regarding their treatment decision. For baseline treatment predisposition, most men were leaning toward surgery (37%), brachytherapy (25%) and radiation (20%), followed by watchful waiting (15%), and hormonal therapy (3%) while 14.5% of men cited no treatment predisposition. No significant demographic differences existed across treatment preference or level of decisional conflict except that men who preferred treatment with curative intent were significantly younger ($p = 0.009$) than those opting for either watchful waiting or lacking a treatment predisposition.

Task 5. Final analyses and manuscript preparation (months 34-36).

Final analyses and manuscript preparation will be performed and written, respectively, at a later date once data collection is complete.

KEY RESEARCH ACCOMPLISHMENTS

Our accomplishments to date center on our excellent accrual rate and outstanding retention rate for the three follow-up assessments.

REPORTABLE OUTCOMES

We have submitted an abstract for presentation at the American Public Health Association (see Appendix).

CONCLUSIONS

This project seeks to aid men in making a decision about early-stage prostate cancer, through the use of a recently developed CD-ROM. Since last year's report, we have expanded the study to include men who already have a diagnosis of early-stage prostate cancer and are interested in participation (i.e., viewing the CD-ROM, but have not yet made a decision about treatment). This has allowed an even greater 'window of opportunity' for accrual. We have also included the Georgetown University Radiation Department and Medical Oncology which have provided several additional referrals that we have not received through the Department of Urology.

We are also considering expanding the study to additional sites, and will seek the necessary approvals from the Department of Defense before proceeding.

It should be noted that although we submitted an addendum to the protocol to the DOD project officer on August 11, 2003 and followed up with multiple emails and phone calls, we have yet to receive the official documentation granting approval. These were two minor protocol changes (addition of a 12 month follow-up and accruing men post-biopsy instead of pre-biopsy). We were told that because of the war in Iraq, approvals were moving much slower than usual.

REFERENCES

None

APPENDICES

APPENDICES

A. APHA Abstract

Background: As the leading newly diagnosed cancer among US men, early stage prostate cancer can be treated with surgery, external beam radiation, brachytherapy, or hormonal therapy. Alternatively, some men prefer not to undergo treatment but to be followed for disease progression ("watchful waiting"). No consensus exists on which treatment is best; instead, factors such as patient age, health status, comorbidity, and preference are considered. Decisional aids may help improve men's knowledge for issues surrounding treatment of this disease, leading to greater satisfaction with treatment choice and concomitant reduction in decisional conflict.

Purpose: To evaluate associations between baseline demographic characteristics, treatment predisposition, and decisional conflict among men diagnosed with early stage prostate cancer participating in a randomized clinical trial of an educational CD-ROM treatment decision aid.

Methodology: English-speaking men without serious cognitive impairment who were recently diagnosed (median = 16.0 days post-diagnosis) with early stage (T1-T2N0M0) prostate cancer and who had not yet made a treatment decision were eligible for study participation. Most patients (85.5%) were enrolled through the Georgetown University Medical Center while several (14.5%) were self-referred via newsletter, support group or family. The Ottawa Decisional Conflict Scale (low-literacy version) and the EuroQol-5D linear health rating scale were used to measure baseline levels of decisional conflict (high ≥ 2 vs. low < 2) and baseline self-rated health status, respectively.

Results: The study participation rate is currently 74.5% (N = 76). The mean age of participants was 63.8 ($\pm$12.2). Subjects were predominantly White (75.0%), married (77.3%), college educated (78.9% college degree or beyond), medically insured (98.7%) and had computer access (97.4%). Over half of men (51.3%) reported another major illness. Mean baseline EuroQol was 80.6 ($\pm$14.5). Forty-seven men (61.8%) reported high baseline decisional conflict regarding their treatment decision. For baseline treatment predisposition, most men chose surgery (37%), brachytherapy (25%) and radiation (20%), followed by watchful waiting (15%), and hormonal therapy (3%) while 14.5% of men cited no treatment predisposition. No significant demographic differences existed across treatment preference or level of decisional conflict except that men who preferred treatment with curative intent were significantly younger ($p = 0.009$) than those opting for either watchful waiting or lacking a treatment predisposition.

Conclusions: Men with early stage prostate cancer may have high decisional conflict and may not have proclivity toward a specific treatment. Decisional aids to help improve prostate cancer knowledge and reduce decisional conflict may benefit men diagnosed with this disease.

B. Revised Consent Form

GEORGETOWN UNIVERSITY
Consent to Participate in Research for Patients

Project Name: Treatment Decision Making in Early-Stage Prostate Cancer: Evaluation of a Computer-Based Patient Educational Tool

Project Coordinator: Tara Lamond, LGSW **Telephone**: 202-687-0435

Principal Investigator: Kathryn L. Taylor, Ph.D. **Telephone:** 202-687-0649

Sponsor: Department of Defense (The United States Army)

The Georgetown University Institutional Review Board has given approval for this research project. For information on your rights as a research subject, call the Institutional Review Board office: 202-687-1506.

Introduction

You are invited to consider participating in this research study. Men who have undergone a prostate biopsy and who have received a diagnosis of early-stage prostate cancer following the biopsy are invited to participate. To test the effectiveness of a computer-based educational tool, men who are diagnosed with early-stage prostate cancer will receive this tool (CD-ROM) that is designed to help them in making an informed treatment decision. The decision to participate or not is yours. If you decide to participate, please sign and date the last line of this form, and return it to us in the enclosed envelope.

The research is being sponsored by the United States Army. Georgetown University is being paid by the United States Army to conduct this study with Kathryn Taylor, Ph.D. as the primary investigator.

Background and purpose of the study

The purpose of this research program is to evaluate an educational computer program that will serve as an addition to the doctor/patient consultation, and that will assist men in making an informed decision about their prostate cancer treatment. We will evaluate factors that play a role in medical decision making among men who have received a diagnosis of early-stage prostate cancer. These issues are important to assess due to the differences in doctor's opinions and the lack of medical evidence regarding the best treatment of early-stage prostate cancer. As each type of treatment has its own set of side effects, and patient age and personal preferences are factors that must be considered, this is an area in which education and discussion are needed in order for men to make an informed treatment decision. If you agree to participate in the research project and are diagnosed with early-stage prostate cancer, you will be asked to participate in a series of four telephone interviews and will receive a computer disk (CD-ROM) with information about prostate cancer and its potential treatments. The interviews will require approximately 15 minutes each to complete, and reviewing the CD-ROM will require between 30 minutes and 4 hours, depending on the amount of time you wish to devote to it. If you do not have access to a computer you will be provided a laptop computer to take home with you for several days. If you do not feel comfortable using a computer on your own, you will be provided assistance by the project staff. We also ask that you give us permission to access your medical records for information about your treatment during the course of the research.

Total number of subjects

About 170 men will take part in this study. Participants in the study are referred to as "subjects." One hundred and seventy subjects will be participating at this site (Georgetown University).

General plan of this study

Participants will be assigned to one of two research groups. A computer will determine which group you will be in through a process that is much like picking a number out of a hat. This process is called randomization.

One group will receive a CD-ROM that will include educational information about prostate cancer and the treatments for prostate cancer, as well as an 'interactive decision aid.' An interactive decision aid is a set of exercises that are designed to help men gain an understanding of their preferences about which treatment choice will result in their greatest satisfaction. The second group will receive a CD-ROM that will contain only the educational information, without the interactive decision aid. The comparison of these two groups will allow the researchers to determine whether the decision aid improves men's decision making abilities, or whether providing the information alone is adequate to assist men in making an informed decision.

Participants will receive a 3.5 inch disk to put into their computer while they are using the CD-ROM and will later return the disk to the investigators. Data will be recorded on this disk indicating how much time participants spent in each of the different sections of the CD. This will be extremely important information, as it will indicate which sections of the CD were most used by the participants, and also which sections received less attention. By having this information, we will be able to potentially streamline the CD in future versions if it appears that certain sections are rarely used. Further, this information will be very important in interpreting group differences on various outcomes, such as knowledge about prostate cancer or treatment selection. A participant could feel it is intrusive for the investigators to know which sections of the CD-ROM he reviewed. If a participant does feel this way, then he simply will not return the 3.5 inch disk to the investigators.

Length of the study for each subject

We expect that you will be in the study for approximately twelve months.

Possible benefits of participating in the study

You may benefit from participating in this study by learning more about the treatments for prostate cancer and by using the computer program to determine which treatment is most suited to your needs and preferences. However, we cannot guarantee that you will experience benefits from participating in this study. You will be assisting the medical community to learn how men make decisions about their treatment for prostate cancer, and what men need to assist them in this process. Other prostate cancer patients may benefit in the future from the information we obtain while you are in this study by determining whether this CD-ROM is helpful to men who are making a treatment decision. The CD-ROM will be yours to keep.

Possible risks of participating in the study

The risks of participating in this research study are minimal. Some patients may find the factual information in the CD-ROM distressing. If you do feel upset after reviewing the information, you can of course talk to your urologist about your treatment options. Further, if you are feeling anxious or depressed about your condition, please contact the study personnel who can provide you with a referral to a prostate cancer support group or to an individual therapist.

Who can participate

This study is designed for men who have undergone a prostate biopsy and who have been diagnosed with early-stage prostate cancer.

Confidentiality of the data collected during the study

All data and medical information obtained about you, as an individual, will be considered privileged and held in confidence. Your name or other identifying information will not be on the information we collect from you or from your medical record, but instead will have a code number and only the researchers will have access to the identifying information (unless the information is required by law). You can refuse to answer specific questions that you find intrusive or too personal and you can refuse to allow the researchers to have access to your medical record. You will not be identified in any presentation of the results. You can withdraw your consent for the use of the telephone interview data or for access to your medical record data at any time without harming your relationship with your doctors or Georgetown University.

Complete confidentiality cannot be promised to subjects, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. It should be noted that representatives of the US Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research.

Individuals from the Georgetown University IRB, Georgetown University Hospital and Medical Center, the U.S. Food and Drug Administration, and the United States Army may look at medical and research records related to this study, both to assure quality control and to analyze data. We will disclose personal information about you to others as required by law.

Data security

Information about your participation in this study is stored in a computer. We will take precautions to protect it from unauthorized disclosure, tampering, or damage through the use of security passwords that will only be available to the research staff for this project. Only authorized users will have access to the data. The interviews you complete will be stored in a locked filing cabinet.

Once the study is complete, hard copies of the data will be kept in a locked storage room in our suite of offices and on the PI's computer. As is customary in the scientific community, the data will be kept for seven years following the final publication that results from this study. Following that, the hard copies of the questionnaires will be shredded and the computer-based copies will be deleted.

New findings

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, and any information that may affect your interest in remaining in the study.

Costs to you for participating

There will be no financial cost to you for participating in this study.

Payments to you for participating

Qualified study subjects will be paid for participating in this study. Participants who are eligible for the entire study will be paid $20 following completion of the first interview, and $20 following completion of the fourth (final) interview, for a total of $40.

Commercial Interest

For your information, HealthMark Multimedia holds the copyright for the computer-based educational tool and has a potential financial interest in the outcome of this study.

Compensation in case of injury

It is extremely unlikely that you will be injured as a result of participating in this study, as it involves reading patient education materials and participating in telephone interviews. We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive emergency medical care at no cost to you. You will not receive any injury compensation, only medical care.

Your rights as a participant in the study

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Should you decide to leave the study, please inform the project staff of your decision (202-687-0435). Should you decide not to participate or to withdraw, your medical care will not be affected nor will your relations with your physicians, other personnel and the hospital or university.

Problems and questions

Call Dr. Taylor at 202-687-0649 during the day if you have questions about the study, any problems, unexpected psychological discomforts, or think that something unusual or unexpected is happening. If you have medically-related questions or concerns, call Dr. John Lynch at 202-687-4922. Call the Georgetown University IRB office at 202-687-1506 with any questions about your rights as a research subject.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not

comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

Investigator's statement

I have fully explained this study to the subject. I have discussed the procedures, the possible risks and benefits, the standard and research aspects of the study, and have answered all of the questions that the subject and the subject's family members have asked.

Signature of investigator _____ Date _____

Subject's consent

I have read the information provided in this Informed Consent Form (or it was read to me by _____). All my questions were answered to my satisfaction. I voluntarily agree to participate in this study.

[Upon signing, you will receive a copy of this form, and the original will become part of your medical record.]

Signature of witness _____ Date _____

Your signature _____ Date _____

Printed name: _____

Permanent address: _____

_____

C. Study Twelve Month Questionnaire

02/17/04

Treatment Decision-Making in Early-Stage Prostate Cancer:
Evaluation of Computer-Based Patient Education and an Interactive Decision Aid

Verbal Informed Consent—Fourth Follow-up Interview (T4-Final)

ID: _____ Date of T4 _____ Interviewer: _____

Time started: _____ Time Ended: _____ Total Time: _____

Hello, my name is_____, and I am calling from Georgetown University. May I please speak with Mr. _____(participant's name)?

IF NOT AVAILABLE/BUSY, ASK:

What would be the best time to call back? Date _____ Time _____ a.m./p.m.

I am calling to conduct our fourth (final) follow-up interview for the prostate research study. I want to first verify that you are still interested in participating in this study. ___yes ____no

IF YES: Continue on.
(If now is not a good time, when is a good time to call back?_____)

IF NO: May I ask why you are not interested in continuing to participate?
____too busy ____not interested in topic ____questions too personal ____other:

It has been about twelve months or so since you received the CD-ROM for this study. This interview should take us about 15 minutes to complete. Is this a convenient time?

IF YES: Begin with T4 interview.
(If now is not a good time, when is a good time to call back? _____)

Do you have any questions about the study at this time?

UCLA Prostate Cancer Index

The following questions are about your urinary, bowel, and sexual function. These questions may or may not apply to you at this time; however, we would like to ask them just to double-check on your current function.

Urinary Function

This section is about your urinary habits. Please consider ONLY THE LAST 4 WEEKS.

1. Over the past 4 weeks, how often have you leaked urine?
   - Every day..... 1
   - About once a week..... 2 (Circle one number)
   - Less than once a week..... 3
   - Not at all..... 4

2. Which of the following describes your urinary control during the last 4 weeks?
   - No control whatsoever..... 1
   - Frequent dribbling..... 2 (Circle one number)
   - Occasional dribbling..... 3
   - Total control..... 4

3. How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks?
   - 3 or more pads per day..... 1
   - 1-2 pads per day..... 2 (Circle one number)
   - No pads..... 3

4. How big a problem, if any, has each of the following been for you? (Circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
5. Dripping urine or wetting your pants	1	2	3	4	5
6. Urine leakage interfering with your sexual activity	1	2	3	4	5

7. Overall, how big a problem has your urinary function been for you during the last 4 weeks?
   - No problem.....1
   - Very small problem.....2
   - Small problem.....3 (Circle one number)
   - Moderate problem.....4
   - Big problem.....5

Bowel Habits

The next section is about your bowel habits and abdominal pain. Please consider ONLY THE LAST 4 WEEKS.

8. How often have you had rectal urgency (felt like you had to pass stool, but did not) during the last 4 weeks?

   More than once a day.....1
   About once a day.....2 (Circle one number)
   More than once a week.....3
   About once a week.....4
   Rarely or never.....5

9. How often have you had stools (bowel movements) that were loose or liquid (no form, watery, mushy) during the last 4 weeks?

   Never.....1
   Rarely.....2 (Circle one number)
   About half the time.....3
   Usually.....4
   Always.....5

10. How much distress have your bowel movements caused you during the last 4 weeks?

    Severe distress.....1
    Moderate distress.....2 (Circle one number)
    Little distress.....3
    No distress.....4

11. How often have you had crampy pain in your abdomen or pelvis during the last 4 weeks?

    Several times a day.....1
    About once a day.....2
    Several times a week.....3 (Circle one number)
    About once a week.....4
    About once this month.....5
    Rarely or never.....6

12. Overall, how big a problem have your bowel habits been for you during the last 4 weeks?

    Big problem.....1
    Moderate problem.....2 (Circle one number)
    Small problem.....3
    Very small problem..... 4
    No problem.....5

Sexual Function

The next section is about your sexual function and sexual satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember, YOUR NAME DOES NOT APPEAR ANYWHERE ON THIS SURVEY. Please answer honestly about the LAST 4 WEEKS ONLY.

How would you rate each of the following during the last 4 weeks?
(Circle one number on each line)

	Very Poor	Poor	Fair	Good	Very Good
13. Your level of sexual desire.....	1	2	3	4	5
14. Your ability to have an erection...	1	2	3	4	5
15. Your ability to reach an orgasm ...	1	2	3	4	5

16. How would you describe the usual QUALITY of your erection?

None at all.....1
Not firm enough for any sexual activity.....2 (Circle one number)
Firm enough for masturbation and foreplay only.....3
Firm enough for intercourse.....4

17. How would you describe the FREQUENCY of your erections?

I NEVER had an erection when I wanted one.....1
I had an erection LESS THAN HALF the time I wanted one.....2
I had an erection ABOUT HALF the time I wanted one.....3 (Circle one number)
I had an erection MORE THAN HALF the time I wanted one...4
I had an erection WHENEVER I wanted one.....5

18. How often have you awakened in the morning or night with an erection?

Never.....1
Seldom (less than 25% of the time).....2
Not often (less than half the time).....3 (Circle one number)
Often (more than half the time).....4
Very often (more than 75% of the time).....5

19. During the last 4 weeks did you have vaginal or anal intercourse?

No.....1
Yes, Once.....2 (Circle one number)
Yes, More than Once.....3

20. Overall, how would you rate your ability to function sexually during the last 4 weeks?

Very poor.....1

Poor.....2
Fair.....3 (Circle one number)
Good.....4
Very Good.....5

21. Overall, how big a problem has your sexual function been for you during the last 4 weeks?

No problem.....1
Very small problem.....2
Small problem.....3 (Circle one number)
Moderate problem.....4
Big problem.....5

02/17/04

Knowledge of Prostate Cancer

Please rate each statement as True (T) or False (F) or Don't Know (DK).

I. Statistics Associated with Prostate Cancer

___1. Usually, prostate cancer grows very quickly compared to other types of cancer.

___2. Prostate cancer is the most common cause of cancer death in men in the U.S.

II. Medical Tests and Tools

___ 3. A man's PSA blood test can be normal even if he has prostate cancer.

___ 4. An abnormal PSA blood test (or high PSA level) does not necessarily mean that prostate cancer is present.

___ 5. A prostate biopsy is used to confirm the diagnosis of cancer.

___ 6. After a man receives treatment for PCa, the PSA level is the main indication that cancer is active again.

III. Watchful Waiting

___ 7. Some experts may suggest that some men with early-stage PCa not receive any treatment for it.

___ 8. In general, doctors believe that older men are more likely to benefit from treatment for prostate cancer compared to younger men.

___ 9. Most men with early-stage prostate cancer who choose to not get treatment will usually die from their disease.

___ 10. For men who select watchful waiting, it is advised to see your doctor every 3-6 months for monitoring of PSA and DRE.

___ 11. All experts agree that compared to watchful waiting, treating early-stage prostate cancer will extend a man's life.

IV. Surgery

___ 12. Surgery is the only method to obtain accurate staging of PCa.

___ 13. Activities may be restricted for up to 4-6 weeks following surgery.

___ 14. Impotence (trouble getting or maintaining an erection) is a common side effect following surgery for prostate cancer.

___ 15. Incontinence (inability to control the flow of urine) can be a side effect of surgery for PCa.

___ 16. Surgery to remove the prostate always results in complete loss of fertility (i.e., the ability to have children).

V. External Beam Radiation

___ 17. External beam radiation removes the cancerous tumor from the body.

___ 18. External beam radiation involves daily outpatient visits for 6-8 weeks.

___ 19. Rectal side effects (e.g., inflammation) are likely with external beam radiation.

___ 20. There is a 30-50% chance of erectile dysfunction over time after external beam radiation.

VI. Brachytherapy/Seed Implantation

___21. Men of all ages are eligible for brachytherapy.

___22. Permanent seed implantation requires a 2-3 day hospital stay.
(Temporary – 2-3 stay; permanent 1 day outpatient)

___ 23. Loss of fertility is likely after brachytherapy.

Use and Evaluation of Prostate Cancer CD-ROM

Since our last interview, have you used the CD-ROM again?

_____ Yes
_____No

If yes, were you hoping to access a particular topic?

_____ Yes
_____ No, I was just looking for general information.

If yes, did the information that was presented in the CD address your questions about prostate cancer and treatment of prostate cancer?

____ Yes, it completely addressed my questions.
____ Yes, it addressed most of my questions.
____ Yes, it addressed some of my questions.
____ No, it did not adequately address my questions.

SATISFACTION WITH DECISION
(Holmes-Rovner Scale)

You have consulted your health care provider about prostate cancer treatment. Answer the following questions about your decision. Please indicate to what extent each statement is true for you AT THIS TIME.

Use the following scale to answer the questions:
1 = Strongly Disagree
2 = Disagree
3 = Neither Agree or Disagree
4 = Agree
5 = Strongly Agree

___ 1. I am satisfied that I am adequately informed about the issues important to my decision.

___ 2. The decision I made was the best decision possible for me personally.

___ 3. I am satisfied that my decision was consistent with my personal values.

___ 4. I expect to successfully carry out (or continue to carry out) the decision I made.

___ 5. I am satisfied that this was my decision to make.

___ 6. I am satisfied with my decision.

Decisional Regret Scale

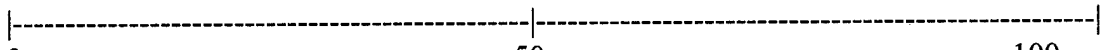
(Items 1-5 from O'Connor scale; Item 6 from Holmes-Rovner; Items 7-8 from Clark et al., 2001, JCO)

Please reflect on the decision that you made about treatment. Please indicate how strongly you agree or disagree with these statements by using the following 5-point scale:

	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
1. It was the right decision	1	2	3	4	5
2. I regret the choice that was made	1	2	3	4	5
3. I would go for the same choice if I had to do it over again	1	2	3	4	5
4. The choice did me a lot of harm	1	2	3	4	5
5. The decision was a wise one	1	2	3	4	5
6. I am satisfied with my treatment decision	1	2	3	4	5
7. I wish I could change my mind about the kind of treatment I received.	1	2	3	4	5
8. I feel I would have been better off if I had received a different treatment.	1	2	3	4	5

Euroqol question

Now I would like for you to think about how good or bad your health is, on a 100 point scale. Zero is the equivalent of the worst health you can imagine, all the up to 100, which is the best health you can imagine. Where would you put yourself on this scale, in terms of your own current health?



0 50 100
(Worst health) (Best health)

Participant's rating: _____

Cancer Worry

Overall, how worried are you about the diagnosis and treatment of prostate cancer?

___not at all worried
___a little worried
___somewhat worried
___extremely worried

Overall, how worried are you about the possibility of dying from prostate cancer?

___not at all worried
___a little worried
___somewhat worried
___extremely worried

Do you have a date scheduled for treatment at this time? Or have you already undergone treatment?
If yes, the date_____
No_____

SF-12

This next set of questions asks for your views about your health.

1. In general, would you say your health is: ___Excellent ___ Very good __Good __Fair __ Poor
   (1) (2) (3) (4) (5)

The following items are about activities you might do during a typical day.

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited
2. Does your health now limit you in terms of moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	1	2	3
3. Does your health limit you in terms of climbing several flights of stairs?	1	2	3

4. During the past 4 weeks, have any problems with your physical health resulted in your accomplishing less than you would like?

   Yes (1) No (0)

5. During the past 4 weeks, have any problems with your physical health limited you in the kind of work or other activities that you do?

   Yes (1) No (0)

6. During the past 4 weeks, have any emotional problems such as depression or anxiety resulted in your accomplishing less than you would like?

   Yes (1) No (0)

7. During the past 4 weeks, have any emotional problems resulted in your not being able to do your work or other activities as carefully as usual?

   Yes (1) No (0)

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
(1)	(2)	(3)	(4)	(5)

These next three questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks. . .

	All	Most	A Good Bit	Some	Little	None
*9. Have you felt calm and peaceful?	1	2	3	4	5	6
10. Did you have a lot of energy?	1	2	3	4	5	6
*11. Have you felt downhearted and blue?	1	2	3	4	5	6
*12. Have you felt happy?	1	2	3	4	5	6
*13. Have you felt nervous?	1	2	3	4	5	6
*14. Have you felt down in the dumps?	1	2	3	4	5	6

15. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

___All of the time ___ Most of the time ___Some of the time ___A little of the time ___None of the time

* *Items are from the MHI-5.*

AT INTERVIEW CLOSE:

Thank you very much for your time today, and for your participation overall in this study. We very much appreciated your willingness and your time to share your responses on our questionnaires. Please do not hesitate to contact us if you should have any questions about this project in the future. Thank you again.